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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,860	11/29/2001	Geert Maertens	2551-69	4135

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EXAMINER

LI, BAO Q

ART UNIT PAPER NUMBER

1648

DATE MAILED: 09/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/995,860

Applicant(s)

MAERTENS ET AL.

Examiner

Bao Qun Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 15-42 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Preliminary amendment has been acknowledged. Claims 1-14 have been canceled. New Claims 15-42 are pending.

Election/Restriction

Upon considering the claimed inventions, Election/Restriction is required under 35 U.S.C. 121:

- I. Claims 15, 36, 40, drawn to a therapeutic HCV vaccine and method for using the same, classified in class 424, subclass 93.1.
- II. Claims 16, 18, 20-26, 36-39, 40, drawn to, a therapeutic HCV vaccine and a method for using the same comprising at least one HCV E1 proteins, classified in class 424, subclass 206. 1.
- III. Claims 17, 19-26 and 41-42, drawn to HCV vaccine comprising at least one HCV E1 proteins form different HCV genotypes, classified in class 530, subclass 395.
- IV. Claims 27-28, drawn to a method for inducing an immune response in a chronic infected mammal, classified in class 435, subclass 3.
- V. Claims 29-30, drawn to a method for clearing HCV viral antigens from the liver of a HCV infected mammal, classified in class 424, subclass 9.31.
- VI. Claim 31-32, drawn to a method for normalizing the liver enzymes in serum of a HCV-infected mammal, classified in class 435, subclass 193.
- VII. Claim 33, drawn to a method for improving the histology of liver of a HCV-infected mammal, classified in class 435, subclass 2.
- VIII. Claim 34, drawn to a method for improving liver disease, classified in class 424, subclass 93.1.
- IX. Claim-36 35, drawn to a method for improving liver inflammation, classified in class 435, subclass 7.93.

The inventions are distinct, each from the other because of the following reasons:

Inventions of groups I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to structurally different products having different structures and

functions, e.g. the product of Group II is a therapeutic HCV vaccine comprising at least one HCV E1 proteins from same HCV genotype, whereas the product of the group III is a therapeutic HCV vaccine comprising at least two HCV E1 proteins from different HCV genotypes.

Inventions of groups IV-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to functionally different methods, they work in different modes and produce different biological effects, e.g. the method of Group IV is a method for inducing an immune response in a chronic infected mammal, whereas, the method of group VI is for normalizing the liver enzymes in serum of a HCV-infected mammal.

Inventions III and V are related as process of using and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be practiced with materially different product or (2) that the product as claimed can be practiced by another and materially different process (MPEP § 806.05(f)). In the instant case, the process as claimed can be practiced with materially different product, such as an Interferon, rather than the polypeptide of HCV E1 protein.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the literature searches required for one of the Groups are not required for another group, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

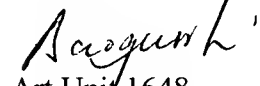
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li



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September 20, 2003